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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,167	12/11/2001	Jonathan A. Usuka	9080-016-999	3878
7590 10/21/2003 PENNIE & EDMONDS LLP 3300 HILLVIEW AVENUE PALO ALTO, CA 94304			EXAMINER LY, CHEYNE D	
			ART UNIT 1631	PAPER NUMBER

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/015,167	USUKA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 14, 15, 39, 40, 62-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16-38, 41-61 and 71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>08 &amp; 09</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's election with traversal of Group I, claims 1-13, 16-38, 41-61, and 71, Species: no weighting of variation versus distance from a locus is required, and linear regression correlation, filed August 07, 2003, is acknowledged.
2. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement directed to the distinct Groups, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Specific to Applicants' traversal of the species election requirement, Applicants' argument has been fully considered and found to be unpersuasive due the species are generally separately analyzed and published, and thus document the undue search burden if searched together.
4. The requirement is still deemed proper and is therefore made FINAL.
5. The species election directed to species set (B), correlation algorithm, has been withdrawn.
6. Claims 1-13, 16-38, 41-61, and 71 are examined on the merits.

### **IDS**

7. Document AX filed August 06, 2002 has not been considered due to said document not being a published document.

### **DOUBLE PATENTING STATUTORY (35 U.S.C. 101)**

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same

invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

9. A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

10. Claims 1 and 9 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 2 of copending Application No. 09/737,918. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

#### **DOUBLE PATENTING NON-STATUTORY**

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

12. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

13. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1, 9-13, 16, 17, 24-26, 34-38, 41, 42, and 48-61 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-32 of copending Application No. 09/737,918. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

15. The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

16. Application No. 09/737,918 is directed to a method, computer program product, and computer system of associating a phenotype with one or more candidate chromosomal regions in a genome of an organism using a phenotypic data structure that represents a difference in a phenotype between different strains of said organism, said genome including a plurality of loci, said method comprising: establishing a genotypic data structure, said genotypic data structure corresponding to a locus selected from said plurality of loci, said genotypic data structure representing a variation of at least one component of said locus between different strains of said organism; comparing said phenotypic data structure to said genotypic data structure to form a correlation value; and repeating said establishing and comparing steps for each locus in said

plurality of loci, thereby identifying one or more genotypic data structures that form a high correlation value relative to all other genotypic data structures that are compared to said phenotypic structure during said comparing step; wherein the loci that correspond to said one or more genotypic structures that form a high correlation value represent said one or more candidate chromosomal regions (Claims 1-32).

### **CLAIM REJECTIONS - 35 USC § 102**

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-10, 12, 13, and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Luo et al. (1992).

3. Luo et al. discloses a method implemented in a computer system comprising Fortran-77 and PASCAL computer programs for interval mapping of quantitative trait loci in an  $F_2$  population wherein the parameters comprises  $P_1$  and  $P_2$  strains (phenotype structure); three genotypes for each quantitative locus (QTL) and each marker gene identified in the genome. Marker linkage map is set up wherein the genome is separated into a series of chromosomal segments and each of which is flanked by two marker loci (genotype structure) (page 237, column 1, lines 1-17). The LOD score is established by scanning all possible sites throughout the interval and the LOD score has its maximum value will be the most likely location of the QTL (high correlation value relative to all other genotypic data structures) (page 237, column 1,

line 37 to column 2, lines 1-4) and the steps are repeated iteratively (page 238, column 2, lines 4-6), as in instant claims 1, 2, 9, 10, 12, 13, and 18.

4. The position of the QTL is centered between two marks (page 237, column 1, diagram), as in instant 5.

5. LOD is plotted wherein the plots are scaled by the length of the marked chromosome in centimorgans (cM) (page 239, column 2, lines 42-48 and Figure 1), as in instant claims 3, 4, and 6-8.

#### **CLAIM REJECTIONS - 35 USC § 103**

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 1-13, 16, 18, 19, 23-38, 41, 43, 44, 48-57, 59-61, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luo et al. (1992) taken with Blum (US 6,132,724 A).

20. Luo et al. discloses the limitations of claims 1-10, 12, 13, and 18 as discussed above.

6. However, Luo et al. does not disclose wherein each element the phenotypic data structure represents a difference in said phenotype between a first cluster of strains of different organisms.

7. Blum discloses in sib pair linkage analysis the DRD<sub>2</sub> A<sub>2</sub> allele (genotype) has been found to associate with a number of behaviors (phenotype); a single point mutation in exon 8 of the DRD<sub>2</sub> gene has been demonstrated; and the cluster of MCMI-II assessed schizoid/avoidant cluster compared to other Axis II diagnostic clusters (antisocial, narcissistic, paranoid) as directed to patients (column 7, lines 35-61), as in instant claims 11, 16, 19, and 44.

8. The method of Blum comprises using linear regression analysis of the mean values (column 104, lines 27-30 and column 105, lines 25-38) and standard deviation (Table 20-D), as in instant claims 23 and 24.

9. The method of Blum further comprises analysis using computerized database such as GenBank database available from the NCBI (column 37, lines 35-42), as in instant claim 25.

10. The ADRAC2C dinucleotide repeat polymorphism sequence is derived from the human genome database (column 176, lines 27-31). The linear regression analysis discussed above is performed using SAS software (column 111, lines 23-30), as in claims 26-38, 41, 43, 48-57, 59-61, and 71.

11. Blum suggests an improvement to overcome such impediments as false positives and un-reproducible data as directed genetic linkage of genes to polygenic disorders (column 21, 18-38). While, Luo et al. discloses a method for modeling genetic mapping of putative genes to polygenic traits (page 236, column 2, lines 5-19). Therefore, the improvement suggested by Blum is directly applicable to the method of Luo et al.



12. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement suggested by Blum to utilize a method of associating a phenotype with a candidate chromosome region(s) as directed to a phenotype wherein the said method comprises a clustering step and a genotype database. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use a method of associating a phenotype with a candidate chromosome region(s) as directed to a phenotype wherein the said method comprises a clustering step and a genotype database as taught by Luo et al. and Blum.

#### **CONCLUSION**

13. NO CLAIM IS ALLOWED.

14. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.


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17. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly  
10/16/03

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER